NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

PFIZER INC., PHARMACIA & UPJOHN COMPANY, and PFIZER HEALTH AB, Plaintiffs, v. IVAX PHARMACEUTICALS, INC., Defendant.	**Hon. Dennis M. Cavanaugh** **OPINION** Civil Action No. 07-CV-00174 (DMC)
IVAX PHARMACEUTICALS, INC., and TEVA PHARMACEUTICALS USA, INC., Counterclaim-Plaintiffs, v. PFIZER INC., PHARMACIA & UPJOHN COMPANY, and PFIZER HEALTH AB, Counterclaim-Defendants.	

DENNIS M. CAVANAUGH, U.S.D.J.:

This matter comes before the Court upon motion by Plaintiffs Pfizer Inc., Pharmacia & Upjohn Company, and Pfizer Health AB (collectively "Pfizer") for summary judgment pursuant to FED. R. CIV. P. 56 regarding Defendants IVAX Pharmaceuticals, Inc. ("IVAX") and Teva Pharmaceuticals USA, Inc.'s ("Teva") (collectively, "Defendants") claim of inequitable conduct; and upon motions by Defendants for summary judgment pursuant to FED. R. CIV. P. 56 regarding their claims of inequitable conduct, no willful infringement and invalidity. Pursuant to FED. R. CIV. P.

78, no oral argument was heard. After carefully considering the submissions of the parties, and based upon the following, it is the finding of the Court that Pfizer's motion for summary judgment regarding inequitable conduct is **granted**; Defendants' motion for summary judgment regarding inequitable conduct is **denied**; Defendants' motion for summary judgment regarding no willful infringement is **granted**; and Defendants' motion for summary judgment regarding invalidity is **denied**.

I. BACKGROUND[1]

A. Procedural History

This case concerns the enforceability of United States Patent No. 5,382,600 (the "'600 Patent") which was issued on January 17, 1995. Pfizer and its subsidiaries are pharmaceutical companies that develop and market drug products. Likewise, Teva is a pharmaceutical company that develops and markets drug products. In 2007, Teva acquired IVAX which is a pharmaceutical company that produces generic versions of drug products. Pfizer instituted the underlying litigation claiming patent infringement under the Hatch-Waxman Act, 35 U.S.C. § 271(e)(2)(A) on January 11, 2007. IVAX's parent company Teva became a party to this suit as a Counterclaim Plaintiff on February 7, 2007. On March 30, 2007, Pfizer joined Teva as a Defendant by filing its Reply and Counterclaim to the Answer and Counterclaims of IVAX and Teva. Pfizer's motion for summary judgment was filed on April 25, 2008. Defendants' motions for summary judgement were also filed on April 25, 2008.

[1] The facts set-forth in this Opinion are taken from the Parties' FED. R. CIV. P. 56.1 statements in their respective moving papers. The facts as set-forth reflect that "[i]n determining whether there are any issues of material fact, the Court must resolve all doubts as to the existence of a material fact against the moving party and draw all reasonable inferences - including issues of credibility - in favor of the nonmoving party." Newsome v. Admin. Office of the Courts of the State of N.J., 103 F. Supp.2d 807, 815 (D.N.J. 2000), aff'd, 51 Fed. Appx. 76 (3d Cir. 2002) (citing Watts v. Univ. of Del., 622 F.2d 47, 50 (D.N.J. 1980)).

B. The ‘600 Patent

There are six inventors named on the ‘600 Patent: Nils A. Jonsson, Bengt A. Sparf, Lemit Mikiver, Pinchas Moses, Lisbeth Nilvebrant, and Gunilla Glas. The inventors assigned the patent application to Kabi Vitrum AB (“Kabi”). Kabi and the six inventors, the ‘600 Patent applicants (“Applicants”), filed their application for what became the ‘600 patent in December 1991.[2] The ‘600 patent claims various substituted diphenylpropylamines and alleges that these compounds have favorable anticholingeric activity. Anticholinergic properties serve to reduce the effects mediated by acetylcholine in the central and peripheral nervous systems, such as emptying of the bladder, production of saliva, slowing of heart rate, and contraction of intestinal smooth muscle. Claim 1 of the ‘600 Patent claims a broad class of 3,3-diphenylpropylamines. Claim 4 of the ‘600 patent claims eleven specific 3,3-diphenylpropylamines. Claim 6 of the ‘600 patent claims the 3,3-diphenylpropylamines of Claim 1 with (+) isomers. *Tolterodine tartrate* or tolterodine is one of the 3,3-diphenylpropylamines compounds claimed as part of the ‘600 patent.

The United States Patent and Trade Office (“PTO”) twice rejected all claims included in the ‘600 Patent application for obviousness. The Applicants disclosed several prior art references including United States Patent No. 3,446,901 (the “Jones ‘901 Patent”), which the examiner found “generically teaches the present compounds and specifically discloses the dimethylamino lower homolog.” In a third action, the PTO rejected all but two of the pending compound claims. The examiner allowed what would become Claims 4 and 6 of the ‘600 Patent. The Applicants responded to the PTO’s determination of the third action by amending their

[2] During the prosecution of the ‘600 Patent, the USPTO changed the patent application number several times the last of which was 5,382, 600. For our purposes here, the ‘600 Patent and all predecessor application numbers which resulted in the ‘600 Patent shall be referred to uniformly as the ‘600 Patent.

application to claim compounds with at least four carbon atoms in the amine group rather than three in an attempt to distinguish the prior art compounds of the Jones '901 Patent. The Applicants stated that "the compounds of the present invention contain at least four carbon atoms on the amine, which provides considerably increased anticholinergic effect." The Applicants further amended their application to include representations of unexpected results over the prior art compounds.

In its review of the fourth action, the examiner stated that the grounds for the prior rejections have not been overcome because the showing of unexpected results was not in declaration form as required by 17 C.F.R. 1.132. The examiner further stated that certain claims would be allowed upon the filing of a declaration attesting to unexpected results over the prior art compounds. The Applicants submitted a supplemental response enclosing a declaration by one of the inventors, Lisbeth Nilvebrant, Ph.D (the "Nilvebrant Declaration"). In her declaration, Dr. Nilvebrant represented that "comparative tests" "established that [claimed] compounds (A) and (B) that were tested are approximately six to seven times better than the [closest] compound" disclosed in the Jones '901 Patent (the Jones Reference Compound) "with respect to anticholinergic activity." Based on the Applicants' showing of unexpected results, the examiner allowed the '600 Patent to issue.

C. The Alleged Infringement

At the present time Pfizer owns the '600 patent, which encompasses various chemical compounds, including the active ingredient in Pfizer's Detrol® brand prescription medication tolterodine tartrate. Detrol® is a prescription medication used to treat symptoms related to overactive bladder. IVAX submitted an Abbreviated New Drug Application ("ANDA"), now

designated as ANDA 77-006, to the Food and Drug Administration ("FDA") seeking permission to market a generic form of tolterodine pursuant to 21 U.S.C. § 355(j). On January 10, 2007, IVAX amended its ANDA to seek approval to manufacture and sell tolterodine prior to the expiration of the '600 patent in 2012. Pursuant to 21 U.S.C. §§ 355(j)(2)(A)(vii)(IV), IVAX submitted a certification which stated that the '600 patent is invalid, unenforceable, or will not be infringed by IVAX's manufacture, use or sale of tolterodine. In January 2007, IVAX notified Pfizer that it had submitted an ANDA regarding tolterodine. Pfizer contends that Defendants' ANDA constitutes infringement of its patent in violation of the Hatch-Waxman Act.

II. FED. R. CIV. P. 56 SUMMARY JUDGMENT STANDARD OF REVIEW

Summary judgment is granted only if all probative materials of record, viewed with all inferences in favor of the non-moving party, demonstrate that there is no genuine issue of material fact and that the movant is entitled to judgment as a matter of law. See FED. R. CIV. P. 56©; Celotex Corp. v. Catrett, 477 U.S. 317, 330 (1986). The moving party bears the burden of showing that there is no genuine issue of fact. See id. "The burden has two distinct components: an initial burden of production, which shifts to the nonmoving party if satisfied by the moving party; and an ultimate burden of persuasion, which always remains on the moving party." Id. The non-moving party "may not rest upon the mere allegations or denials of his pleading" to satisfy this burden, but must produce sufficient evidence to support a jury verdict in his favor. See FED. R. CIV. P. 56(e); see also Matsushita Elec. Indus. Co. v. Zenith Radio Corp., 475 U.S. 574, 586 (1986). "[U]nsupported allegations in memorandum and pleadings are insufficient to repel summary judgment." Schoch v. First Fid. Bancorporation, 912 F.2d 654, 657 (3d Cir. 1990). "In determining whether there are any issues of material fact, the Court must resolve all

doubts as to the existence of a material fact against the moving party and draw all reasonable inferences - including issues of credibility - in favor of the nonmoving party." Newsome v. Admin. Office of the Courts of the State of N.J., 103 F. Supp.2d 807, 815 (D.N.J. 2000), aff'd, 51 Fed. Appx. 76 (3d Cir. 2002) (citing Watts v. Univ. of Del., 622 F.2d 47, 50 (D.N.J. 1980)).

III. DISCUSSION

A. Inequitable Conduct

As a defense to Pfizer's willful patent infringement claim, Defendants assert that the '600 Patent is invalid because of inequitable conduct. Pfizer denies any inequitable conduct and has submitted a motion for summary judgment regarding this issue. Defendants have also submitted a motion for summary judgment regarding inequitable conduct.

I. Applicable Law

It is well settled that "[e]ach individual associated with the filing and prosecution of a patent application has a duty of candor and good faith in dealing with the [Patent] Office, which includes a duty to disclose to the Office all information known to that individual to be material to patentability." McKesson Info. Solutions, Inc. V. Bridge Medical, Inc., 487 F.3d 897, 913 (Fed. Cir. 2007). (quoting 37 C.F.R § 1.56(a)). A breach of this duty constitutes inequitable conduct, which subjects any resulting patent to nullification. To invalidate a patent because of failure to comply with the duty of candor and good faith, it must be demonstrated that the applicant, "with intent to mislead or deceive the examiner, fail[ed] to disclose material information or submit[] material false information to the PTO during prosecution." Id. The materiality and intent components of inequitable conduct must be proven by clear and convincing evidence for a patent to be rendered invalid. Id.

a. Materiality

Materiality can be determined under one of two standards, the "reasonable examiner" standard or the standard adopted by the PTO at 37 C.F.R. § 1.56(b). Digital Control Inc. v. Charles Mach. Works, 437 F.3d 1309, 1316 (Fed. Cir. 2006); Cargill, 476 F.3d at 1364. The reasonable examiner standard, which was the only standard during the pendency of the '600 Patent was established in part based on the pre-1992 PTO regulations and provides that information is material for purposes of inequitable conduct if there is "a substantial likelihood that a reasonable examiner would consider it important in deciding whether to allow the application to issue." Honeywell Int'l Inc. v. Universal Avionics Sys. Corp., 488 F.3d 982, 1000 (Fed. Cir. 2007). The amended PTO Rule 56 provides that information is "material to patentability" if:

> (1) It establishes, by itself or in combination with other information, a prima facie case of unpatentability of a claim; or
> (2) It refutes, or is inconsistent with, a position the applicant takes in:
> (I) Opposing an argument of unpatentability relied on by the Office, or
> (ii) Asserting an argument of patentability.

37 C.F.R. § 1.56(b). An applicant has no duty to submit information that is not material to patentability, or that is cumulative of information already disclosed. 37 C.F.R. § 1.56(b); FMC Corp. v. Manitowoc Co., 835 F.2d 1411, 1415 (Fed. Cir. 1987).

b. Knowledge and Intent to Deceive

The intent to deceive element requires consideration of all evidence including evidence indicative of good faith. See Paragon Podiatry Lab., Inc. V. KLM Labs., Inc., 948 F.2d 1182, 1189 (Fed Cir. 2006). "'[S]moking gun' evidence is not required in order to establish an intent to deceive." Paragon Podiatry Lab., Inc., 948 F.2d at 1189. The Court looks at all facts

surrounding an applicant's overall conduct to infer culpability because "[i]ntent rarely can be, and need not be, proven by direct evidence." Cargill, Inc. v. Canbra Foods, Ltd., 476 F.3d 1359, 1364 (Fed. Cir. 2007). There however, must "be a factual basis for a finding of deceptive intent." Purdue Pharma L.P. v. Endo Pharms. Inc., 438 F.3d 1123, 1134 (Fed. Cir. 2005). More than an omission of material information is necessary, "clear and convincing evidence of conduct sufficient to support an inference of culpable intent is required." Northern Telecom, Inc. V. Datapoint Corp., 908 F.2d 931, 939 (Fed. Cir. 1990). Furthermore, "materiality does not presume intent, which is a separate and essential component of inequitable conduct." Allen Eng'g Corp. V. Bartell Indus., Inc., 299 F.3d 1336, 1352 (Fed. Cir. 2002).

c. Balancing of the Equities

If materiality and intent are demonstrated by clear and convincing evidence, a Court must then "balance the equities to determine whether the patentee has committed inequitable conduct that warrants holding the patent unenforceable." Cargill, 476 F.3d at 1364. Under the balancing test, "[t]he more material the omission or the misrepresentation, the lower the level of intent required to establish inequitable conduct, and vice versa." Id. (quoting Critikon, Inc. v. Becton Dickinson Vascular Access, Inc., 120 F.3d 1253, 1256 (Fed. Cir. 1997)).

ii. Defendants Allegations of Inequitable Conduct

a. False and Misleading Statements Contained in the Nilvebrant Declaration

Defendants argue that the Nilvebrant Declaration contains information that is false and misleading. Of the challenged assertions made in the Nilvebrant Declaration, the most important is that compounds (A) and (B) are six to seven times better than the tested Jones compound. Defendants assert that the tests upon which this statement is based are inaccurate. Pfizer rebuffs

Defendants' claims on the grounds that Defendants have not demonstrated or explained how the alleged inaccuracies "refute" or are "inconsistent with" Dr. Nilvebrant's statement concerning compounds (A) and (B). Moreover, Pfizer argues that Defendants overstate the importance of Dr. Nilvebrant's declaration. Pfizer highlights that by the time Dr. Nilvebrant submitted her declaration, the examiner had already indicated that two claims in the '600 Patent, Claims 4 and 6, would be allowed. The crux of Defendants' inequitable conduct claim is not that Dr. Nilvebrant's statement about the anticholinergic activity of compounds (A) and (B) is false but rather that it has not been established sufficiently to substantiate a claim of unexpected results.

Defendants additionally claim that some of the conclusions presented in the Nilvebrant Declaration are not based on sound scientific rigor and are therefore scientifically unreliable. Defendants support this position with two arguments. The first argument is that a "comparative" study was never performed. Defendants assert that because the tests relied upon by Plaintiffs were performed in isolation by different people years apart from each other, these tests cannot be considered as comparative. Defendants point out that Dr. Nilvebrant does not consider "tests done two years apart by two different people" to be "comparative tests." Defendants' second argument is that Applicants relied on improper research procedures and that some of the test results are inaccurate. Defendants call attention to the fact that neither Exhibit A nor Table 1 of the '600 Patent application indicate the standard error of the mean or the number of tests performed to obtain the results reported. Defendants further claim that in contradiction to Dr. Nilvebrant's general practice and scientific research principals, the compounds at issue were not tested three times. Furthermore, Dr. Nilvebrant acknowledges that with respect to the Jones Reference Compound, there may have been errors made during testing and/or the reporting of

data to the PTO.

Defendants argue that despite these issues, Applicants, through the Nilvebrant Declaration, unequivocally represented that "comparative tests" "establish that compounds (A) and (B) are approximately six to seven times better than the compound according to Jones, with respect to anticholinergic activity..."

Pfizer makes six assertions to refute Defendants' challenges to the veracity of the data reported in the '600 Patent application. Pfizer argues that: (1) the scientific rigor required to satisfy the FDA that a drug is safe is more stringent than that required to get a patent from the PTO and that Dr. Nilvebrant's conclusion was qualified with the term "approximately;" (2) the Applicants did compare data so the use of the term "comparative test" was not misleading; (3) any error was harmless and certainly not intentional; (4) Defendants did not demonstrate that the data was wrong or was otherwise unreliable; (5) there is consistency among the tests performed and the expected graph shape occurred; and (6) Defendants have taken Dr. Nilvebrant's statements out of context and that her statements taken in context do not support Defendants' position.

The Federal Circuit has established that information provided in declarations submitted in response to rejections of patent applications are material. See Pharmacia Corp., 417 F.3d at 1373. In the present case, the examiner has repeatedly rejected Applicants' claims for obviousness over the Jones '901 Patent. The Nilvebrant Declaration was submitted for the specific purpose of demonstrating unexpected results in order to overcome the examiner's fourth rejection. A reasonable examiner would have wanted to know about the technical deficiencies highlighted by the Defendants because they inform the reliability of the research and data

provided to the examiner and the reliability of the conclusions asserted by Applicants. Therefore, the aspects of the Nilvebrant Declaration in question are material.

The facts of record however, do not demonstrate that Applicants intended to deceive the PTO. Although Dr. Nilvebrant and the other Applicants may have been aware of some of the technical deficiencies discussed in Defendants papers; it has not been demonstrated that these technical issues were omitted from the application in an attempt to mislead the examiner. Applicants knew that three tests were usually performed before reaching conclusions and that in this case this practice was not followed. Nonetheless, there is no evidence to suggest that Applicants believed that the information they provided to the PTO was less than accurate because of this fact. Defendants and Applicants clearly differ on the definition of comparative testing; however, Defendants have not demonstrated that Applicants intentionally mis-characterized the data reported as "comparative" to make the data seem more persuasive than it is. Therefore, Defendants have not demonstrated that the Nilvebrant Declaration was submitted in an attempt to mislead the PTO.

b. Intentional Withholding of Prior Art

Defendants assert inequitable conduct based on the argument that Applicants intentionally withheld material prior art, namely a German patent and a Swedish patent. Defendants allege that had this information been disclosed, Applicants could not have overcome it. Applicants claim that they did not provide the German and Swedish references because those references were cumulative of the Jones references which they did provide. Applicants turn to conclusions made by Defendants' expert to demonstrate the cumulative nature of the German and Swedish references. It is well established that a patent applicant has no obligation to disclose

cumulative information to the PTO, because cumulative information is not material by definition. 37 C.F.R. § 1.56(b); Tap Pharm. Prods., Inc. v. Owl Pharms., L.L.C., 419 F.3d 1346, 1351 (Fed. Cir. 2005).

Applicants' demonstration of the cumulative nature of the German and Swedish references is sufficient to demonstrate that they had no duty to disclose these references. Applicants' demonstration certainly establishes that they in good faith believed that they did not have to disclose these references, thus negating an intent to deceive.

c. Misrepresentations of Compounds Disclosed in the Jones '901 Patent

Defendants state that Applicants did not disclose the anticholinergic characteristics of some of the compounds contained in the prior art. Specifically, Defendants argue that Applicants knew that the compounds identified in the Jones '901 Patent had anticholinergic characteristics and that persons skilled in the art would have expected compounds of the type disclosed in the Jones '901 Patent to have anticholinergic effect. Defendants claim that Applicants misled the examiner by representing that the Jones Patent encompasses antidepressant agents.

Applicants respond by noting that the Jones '901 Patent applicants described the Jones '901 application as concerning antidepressant agents and therefore, their reference to the same was not misleading to the examiner and was certainly not intended to be misleading. Applicants further state that they did provide the examiner with information about the anticholinergic characteristics of compounds in the prior art. The Court agrees with Applicants on both assertions, the primary purpose of the Jones '901 Patent was to obtain a patent over compounds with antidepressant characteristics and was described as such by its applicants. See Ortho-McNeil Pharm., Inc. V. Mylan Labs., Inc., 2008 WL 834402 at *4 (Fed. Cir. Mar. 31, 2008)

(because an applicant repeats the disclosures of the references instead of characterizing the compounds themselves, there was no misrepresentation where a challenger argues a broader description would have been more appropriate). Moreover, as evidenced by the Nilvebrant Declaration, Applicants did disclosed the anticholinergic characteristics of at least one of the compounds in the prior art. Since Defendants' arguments are unfounded, there is no need for the Court to undertake a full inequitable conduct analysis.

_____d. Misrepresentations Concerning the Closest Prior Art

Defendants' challenge Dr. Nilvebrant's statement regarding the anticholinergic activity of compounds (A) and (B) as compared to the Jones Reference Compound on the grounds that the Jones compound tested was not the closest compound identified in the prior art. Pfizer argues that Applicants tested the Jones compound that was, from a chemical structure perspective, the closest prior art.

Defendants arguably raise a question of scientific fact as to which Jones'901 Patent compound is the closest prior art, however, Applicants had a sound reason for why they selected the compound tested. Defendants have not alleged facts to suggest that Applicants intentionally chose to test a compound that was not the closest prior art. Therefore, Defendants' argument fails to satisfy the intent requirement. Moreover, the examiner who was informed of all of the identified compounds in the Jones '901 Patent did not determine that the compound selected was not the closest prior art compound. Hence, Defendants closest prior art compound argument does not provide the requisite grounds to find that the Applicants' conduct was inequitable.

e. Misrepresentations as to the Identity of Compound A

Defendants allege that Applicants intentionally failed to disclose that compound A had already been disclosed by the Jones '901 Patent and was also claimed by a related prior art patent before the PTO known as GB 1,169,945 (the "British '945 Patent"). Applicants admit that compound (A) is one of the large number of possible compounds that fall within the generic formula of the Jones '901 Patent and the British '945 Patent. Applicants however, point out that compound (A) is not diagramed or discussed in either of these patents, and thus these patents do not "disclose" or "claim" compound (A). To support this argument, Applicants correctly rely on In re Baird for the proposition that a generic formula does not serve as a specific disclosure of all compounds that fall within it for purposes of determining the closest compound. 16 F.3d 380, 382-83 (Fed. Cir. 1994).

Even more damaging to Defendants' allegation is the fact that once a patent applicant discloses a prior art reference to the examiner, the applicant has satisfied the duty of disclosure under Rule 56. See Fiskars Inc. v. Hund Mfg. Co., 221 F.3d 1318, 1327 (Fed. Cir. 2000). The Applicants disclosed the Jones '901 Patent in their initial application thus satisfying their duty. The PTO was on notice of the general formula Defendants note includes compound A and could have reached the same conclusion as Defendants but did not.

iii. Summary Judgment Analysis

Defendants raise several technical concerns with the '600 Patent application. These concerns demonstrate that the conclusions made in the Nilvebrant Declaration should have been qualified. Moreover, a reasonable examiner most likely would have wanted to consider these issues when making his/her determination. Nonetheless, even giving the Defendants the benefit

of the doubt and despite the apparent materiality of the issues raised, these issues do not demonstrate that Applicants intended to mislead or deceive the examiner and thus they do not provide grounds for the Court to find that Applicants' conduct was inequitable. Therefore, Defendants have not demonstrate inequitable conduct. Defendants' motion for summary judgment is **denied** and Pfizer's motion is **granted**.

B. Willful Infringement

Defendants move for summary judgment on the issue of "willful" infringement based on the proposition that a claim of willful infringement is not permissible as a matter of law when the infringement alleged only arises under the Hatch-Waxman Act. In response, Pfizer argues that its willful infringement claim is not predicated solely on Defendants' ANDA filing, but rather on the totality of the circumstances.

The Hatch-Waxman Act was enacted in 1984. The Act amended the Food, Drug and Cosmetic Act ("FDCA") to facilitate the availability of generic pharmaceuticals. One of the ways the FDCA facilitates the availability of generic pharmaceuticals is by allowing generic manufactures to avoid the costly and lengthy FDA application and approval process by filing an ANDA. An ANDA "in effect, piggy-back[s] on the safety and effectiveness information" submitted in a brand name manufacturer's ("BNM") New Drug Application ("NDA"). Celgene Corp. v. Teva Pharms. USA, Inc., 412 F. Supp. 2d 439, 440-41 (D.N.J. 2006). The FDCA created a specific infringement action for instances where a BNM determines that an ANDA, if approved, would infringe on its patent rights. See 35 U.S.C. § 271(e)(2).

Infringement under the Act is not the same as traditional infringement in that the statute provides a narrow range of remedies. These remedies are: (I) an order precluding FDA approval

of the ANDA until the expiration of the patent-in-suit, (ii) an injunction against sale of the infringing product, and (iii) compensatory damages if the generic product has actually been launched. 35 U.S.C. § 271(e)(4). Defendants correctly argue that the remedies for infringement as defined under the FDCA are limited to those enumerated above. Moreover the FDCA does not allow for a declaration of willful infringement.

Defendants' position is further supported by the Federal Circuit's Glaxo holding that the mere filing of an ANDA or a paragraph IV certification cannot support a finding of willful infringement. Glaxo Group, Ltd. v. Apotex, Inc., 376 F.3d 1339, 1349-51 (Fed Cir. 2004). In Glaxo, the Federal Circuit noted that the FDCA created an artificial form of infringement and prescribed limited remedies which do not include a finding of willfulness. See id. at 1349-50.

Defendants also rely on Janssen, a case decided this year in this jurisdiction. In Janssen, plaintiffs filed suit under 35 U.S.C. §271(e)(2) alleging willful infringement based upon the defendant's ANDA filing and paragraph IV certification, as did Plaintiffs in the instant action. Janssen v. Barr Labs., Inc., No. 03-891, 2007 WL 323558, at *3 n.1 (D.N.J. Feb. 4, 2008). The Janssen Court dismissed the willfulness claim, noting that "district courts continually dismiss willful infringement claims based solely on an ANDA filing and relevant paragraph IV certifications" and that the District of New Jersey "has never sustained a willful infringement claim brought under 35 U.S.C. § 271(e)(2)." Id. at *3.

As a general rule, the filing of an ANDA does not substantiate a claim of willful infringement. Pfizer however, correctly cites case law which states that in certain circumstances attorney fees for willful infringement might be appropriate. See Novartis Pharm. Corp. v. Teva Pharms. USA, Inc., No. 05-1887, 2005 WL 3664014, at *2 (D.N.J. Dec. 30, 2005). In its

response, Pfizer attempts to distinguish Glaxo by arguing that Glaxo is limited to cases were there is an ANDA filing and no other extenuating circumstances.

Here, Pfizer argues that Plaintiffs' claim of willful infringement is warranted because Teva amended its defenses and counterclaims in a previous action based on information it received from IVAX that was restricted and confidential pursuant to a Protective Order. Pfizer also raises the fact that Teva did not timely notify Pfizer of its intent to withdraw its ANDA causing Pfizer to unnecessarily prepare a response to a summary judgment motion filed by Teva. Lastly, Pfizer takes issue with Defendants' exchange of protected information generally.

Pfizer has filed a willful infringement case based solely on the fact that Defendants filed an ANDA. While Pfizer raises possible violations of Court Orders, willful infringement is not the proper vehicle to address these alleged violations. Likewise, though Pfizer claims that because of misconduct by Teva it unnecessarily expended funds to appose a summary judgment motion in a related case, this allegation, even if true, does not provide grounds to support a finding of willful infringement. The facts relevant to the issue of willful infringement are sufficiently settled. For purposes of this motion, the Court accepts as true Pfizer's allegations as to Defendants' conduct with respect to protected information and delay. The issue then becomes, as a matter of law do the facts pled warrant a finding of willful infringement? The relevant facts support a conclusion that Defendants have filed an ANDA, which if granted might violate the '600 Patent. As has been expressed by the Federal Circuit, the filing of an ANDA application is not sufficient to support a finding of willful infringement. Therefore, the Court finds that Plaintiffs have not demonstrated that Defendants willfully infringed their patent. The Court **grants** Defendants' motion for summary judgment.

C. Invalidity Because of Obviousness

Defendants' last motion for summary judgment is based on obviousness. Plaintiffs argue that Defendants infringed Claim 4 of the '600 Patent, which encompasses eleven specific diphenylpropylamine compounds, one of which is tolterodine tartrate; and Claim 6 of the '600 Patent, which claims the (+) isomers of the genus of diphenylpropylamine compounds claimed in Claim 1. Defendants seek to produce a generic version of Pfizer's Detrol® medication. Two key elements of Detrol® are tolterodine tartrate of Claim 4 and the (+) isomers of Claim 6 of the '600 Patent. Defendants correctly argue that if at least one compound of Claims 4 and 6 of the '600 Patent are informed by prior art this would be sufficient to invalidate these claims. See Titanium Metals Corp. of Am. v. Banner, 778 F.2d 775, 782 (Fed. Cir. 1985).

Under 35 U.S.C. § 103, a patent is invalid for obviousness "[i]f the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which the subject matter pertains." Obviousness is a legal determination, which turns on the objective analysis of underlying factual inquiries. Forest Labs., Inc. v. Ivax Pharms., Inc., 501 F.3d 1263, 1269 (Fed. Cir. 2007). Specifically, four factual issues known as the Graham factors must be considered: (1) the scope and content of the prior art; (2) the level of ordinary skill in the art; (3) the differences between the claimed subject matter and the prior art; and (4) secondary considerations of objective indicia of non-obviousness. Id. (citing Graham v. John Deere Co., 383 U.S. 1, 17018 (1966)). With regard to the third Graham factor, the Federal Circuit has proscribed employing "hindsight" analysis. See In re Kotzab, 217 F.3d 1365, 1369-70 (Fed. Cir. 2000). The party seeking to invalidate the patent must demonstrate obviousness by

clear and convincing evidence. Typeright Keyboard Corp. V. Microsoft Corp., 374 F,3d 1151, 1157 (Fed. Cir. 2004). The Federal Circuit has clearly stated that the burden of proof for the issue of patent validity never shifts. Am. Hoist & Derrick Co. v. Sowa & Sons, Inc., 725 F.2d 1350, 1360 (Fed. Cir. 2007).

The Federal Circuit has clarified that obviousness of chemical compounds in the wake of KSR Int'l Co. v. Teleflex, Inc., 127 S.Ct. 1727 (2007), requires a "showing that the prior art would have suggested making the specific molecular modifications necessary to achieve the claimed invention." Takeda Chem. Indus., Ltd. v. Alphapharm Pty., Ltd., 492 F.3d 1350, 1356 (Fed. Cir. 2007) (citations omitted). In addition, despite Defendants' interpretation of KSR, even where prior art was not considered by the examiner, the presumption of patent validity and the clear and convincing evidence standard have not been disturbed. See Torpharm, Inc. v. Ranbaxy Pharms., Inc., 336 F.3d 1322, 1329-30 (Fed. Cir. 2003).

Defendants cite two prior art references, Dr. John Long's Stereochemical Factors and the '890 patent to substantiate their claim that a person with ordinary skill in the art knew or could anticipate the compounds identified in Claims 4 and 6 of the '600 Patent. Pfizer argues that while these references inform a person with ordinary skill in the art about the anticholingeric properties of certain compounds, they do not suggest anything about the selectivity of the compounds claimed in the '600 Patent. Likewise, the prior art references do not provide direction as to the placement of hydroxyl specifically on the phenyl ring of a diphenylpropylamine as a means of making a compound more selective in its receptor binding. Pfizer argues that the selectivity of the claimed compounds is the key to their usefulness as a medication for over active bladder.

Pfizer further agues that the claimed compounds have structural features that are not informed by the prior art. Pfizer asserts that even if there are similarities between the claimed compounds and the prior art, the Defendants would still need to demonstrate the second part of the necessary showing. If a patent challenger can demonstrate that the compound in question is structurally similar to prior art, the challenger must then demonstrate "that the prior art would have suggested making the specific molecular modification necessary to achieve the claimed invention." Takeda, 492 F.3d at 1356. Pfizer contends that Defendants cannot make this showing thus negating obviousness of the claimed compounds.

Pfizer buttresses its opposition to Defendants' claim of obviousness by highlighting the apparent "hindsight" nature of the claim. Pfizer argues that there is no reason why a person of ordinary skill in the art would have considered Stereochemical Factors when seeking to create a selective anticholingeric compound. Pfizer further argues that reverse engineering demonstrates how selectivity is achieved but without the claimed compounds as a blueprint, the method to achieve selectivity is not intuitive.

Moreover, Pfizer raises secondary considerations of non-obviousness regarding the need and prior lack of availability of a product to treat over active bladder, the effort expended to create the claimed compounds, and the commercial success of Detrol®. Defendants improperly challenge the considerations of these factors despite clear Federal Circuit guidance that "[i]t is entirely appropriate...for the patent owner to point to secondary considerations with respect to any commercial embodiment of the claim."

It is well-settled that "[w]hat a reference teaches is a question of fact." In re Bell, 991 F.2d 781, 784 (Fed. Cir. 1993). Whether the references cited by Defendants teach the specific

structure of the claimed compounds; and whether a person of ordinary skill in the art would, in fact, have been motivated to combine these references to produce the claimed compounds with selective anticholinergic activity are all issues of material fact in dispute. Furthermore, Pfizer presents secondary considerations which also raise questions of fact. As a result of the questions of fact presented in this matter, summary judgment is not appropriate as to the invalidity of the '600 Patent because of obviousness and Defendants' motion is **denied**.

IV. CONCLUSION

For the reasons stated, it is the finding of the Court that Defendants' motion for summary judgment regarding inequitable conduct is **denied**; Pfizer's motion for summary judgment regarding inequitable conduct is **granted**; Defendants' motion for summary judgment regarding no willful infringement is **granted**; and Defendants' motion for summary judgment regarding invalidity is **denied**. An appropriate Order accompanies this Opinion.

S/ Dennis M. Cavanaugh
Dennis M. Cavanaugh, U.S.D.J.

Date: December 9, 2008
Orig.: Clerk
cc: All Counsel of Record
Hon. Mark Falk, U.S.M.J.
File